K090556

510(k) Summary

APR 30 2009

Submission Date:	23 February 2009
Submitter:	Spacelabs Healthcare Medical Equipment (Suzhou) Co., Ltd. Building 30, West Wing Chuang Tou Industrial Square, Yang Xian Road
Submitter Contact:	Jennifer Cui Phone: 011-086-0512-87178286 Fax: 011-086-0512-87178278 Email: Jennifer.Cui@spacelabs.com
Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Trade Name:	Spacelabs *élance* Vital Signs Monitoring System
Common Name:	Patient Physiological Monitor (with arrhythmia detection or alarms)
Classification Name:	Monitor, physiological, patient (with arrhythmia detection or alarms)
Classification Regulation:	21 CFR §870.1025
Product Code:	MHX

Substantially Equivalent Devices:

Spacelabs élance Vital Signs Monitoring System	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
ECG component Respiration component Non-invasive blood pressures component Invasive blood pressures component Temperature component	K001775	Zoe Medical Nightingale Monitoring System
Expired and/or inspired CO_2 component	K060065	Oridion Capnostream 20
Functional arterial oxygen saturation component	K033296	Masimo Corporation SET Rad 5 MS-11 board
Arrhythmia detection and invasive pressure monitoring (IBP)	K062144	Invivo Escort M8 Vital Signs Patient Monitor Model 3810
Functional arterial oxygen saturation component	K012891	Nellcor Oximax N-595 pulse oximeter

Device Description:

The Spacelabs Healthcare Medical Equipment (Suzhou) Co., Ltd. (Spacelabs) *élance* Vital Signs Monitoring System (*élance*) is a family of portable patient monitors intended to be used by clinicians and medical qualified personnel for monitoring ECG, Respiration, NIBP, Temperature, SPO_2, Invasive Blood Pressure and $EtCO_2$. Models within the Spacelabs *élance* family come in two different sized viewing areas (10.2" and 12.1"), two different housing colors (white and black) and offer selected monitoring features. See the following Product Configuration List for the identified models and Spacelabs defined monitoring features.

Central Station:

A software package (93900) is available for use with customer acquired computer based on specifications provided by Spacelabs Medical. This package allows monitoring of the *élance* at a central workstation.

Technology Comparison:

The *élance* utilizes the same or similar technology for each parameter as utilized by the predicate devices.

Intended Use:

The Spacelabs *élance* Vital Signs Monitor is indicated for use in patient populations for:

- Adult
- Pediatric

The Spacelabs *élance* Vital Signs Monitor facilitates the monitoring of:

- ECG with arrhythmia detection
- Respiration
- Non-invasive blood pressures
- Invasive blood pressures
- Body temperature
- Functional arterial oxygen saturation, and
- Expired and/or inspired CO2.

The Spacelabs *élance* Vital Signs Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Performance Testing:

Sterilization Validation	The Spacelabs *élance* is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.
Shelf Life Testing	The Spacelabs *élance* is not sterilized or sterilizable, and therefore this section does not apply to the monitor itself.
Biocompatibility Testing	The Spacelabs *élance* has no patient contact materials, and therefore this section does not apply to the monitor itself.
Software Testing	Software for the Spacelabs *élance* was designed and developed according to a robust software development process, and was rigorously verified and validated. Test results indicated that the Spacelabs *élance* complies with its predetermined specification.
Electrical Safety	The Spacelabs *élance* was tested for patient safety in accordance with applicable Standards. Test results indicated that the Spacelabs *élance* complies with its predetermined specification.
Electromagnetic Compatibility Testing	The Spacelabs *élance* was tested for EMC in accordance with applicable Standards. Test results indicated that the Spacelabs *élance* complies with its predetermined specification.
Performance Testing – Bench	The Spacelabs *élance* was tested in accordance with internal requirements and procedures, and test results indicated that the device complies with the predetermined requirements. This testing includes performance and functional, environmental, and shipping and transportation testing.
Performance Testing – Animal:	Animal performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Spacelabs *élance*.

Performance Testing – Clinical:	Clinical performance testing was not performed and is not necessary to demonstrate safety and effectiveness of the Spacelabs *élance.*
Conclusion	Based upon a comparison of devices and performance testing results, the Spacelabs *élance* is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Spacelabs Healthcare Medical Equipment (Suzhou) Co., Ltd.
c/o Mr. Thomas Kroenke
Speed To Market, Inc.
P.O. Box 3018
Nederland, CO 80466

Re: K090556
Trade/Device Name: *élance* Vital Signs Monitoring System; and, *élance* Central Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 23, 2009
Received: March 2, 2009

Dear Mr. Kroenke:

This letter corrects our substantially equivalent letter of April 30, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Spacelabs Healthcare, Inc. (Spacelabs) *élance* Vital Signs Monitoring System

Indications for Use: The Spacelabs *élance* Vital Signs Monitor is indicated for use in patient populations for:

- Adult
- Pediatric

The Spacelabs *élance* Vital Signs Monitor facilitates the monitoring of:

- ECG with arrhythmia detection
- Respiration
- Non-invasive blood pressures
- Invasive blood pressures
- Body temperature
- Functional arterial oxygen saturation, and
- End title CO_2.

The Spacelabs *élance* Vital Signs Monitor is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090556